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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/786,425 | 02/25/2004 | Joseph A. Sorge | 225436/1163 | 2805 |
| 27495 | 7590 | 08/22/2006 | EXAMINER | |
| PALMER & DODGE, LLP KATHLEEN M. WILLIAMS / STR 111 HUNTINGTON AVENUE BOSTON, MA 02199 | | | KAM, CHIH MIN | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1656 | |

DATE MAILED: 08/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/786,425

Applicant(s)

SORGE ET AL.

Examiner

Chih-Min Kam

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 4/9/04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Informalities

The disclosure is objected to because of the following informalities:

1. The specification recites nucleotide and amino acid sequences at pages 20 and 47, however, sequence identifiers "SEQ ID NO:" are not provided. Appropriate correction is required.

Claim Objections

2. Claims 1 and 5 are objected to because the claim recites "R. reniformis", a fully spelled out word should be indicated in the first occurrence.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 2-4 and 6-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
4. Claims 2-4 and 6-10 are indefinite because the claim is dependent from itself or a non-existing claim. Claims 7-8 are included in the rejection because they are dependent on a rejected claim and do not correct the deficiency of the claim from which they

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1 and 3-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zolotukhin *et al.* (U.S. Patent 5,874,304, published on February 23, 1999) in view of Bryan *et al.* (U. S. Patent 6,232,107, filed March 26, 1999).

Zolotukhin *et al.* disclose humanized green fluorescent protein (GFP) genes adapted for expression in mammalian and human cells, and the humanized GFP genes are prepared by incorporating codons preferred for use in human genes into the DNA sequence, humanized GFP expression constructs, and methods of making and using such genes, where the humanized genes are preferably humanized versions adapted from the A. Victoria GFP gene, but other GFP gene sources are not excluded (column 2, lines 11-33; claim 1 of the patent). The reference also indicates that the GFP from *Acquorea* and that of the sea pansy *Renilla reniformis* share the same chromophore, where *Renilla* GFP has a single absorbance peak at 498 nm with about 5.5 fold greater monomer extinction coefficient than the major 395 nm peak of the *Acquorea* GFP (column 16, lines 4-15). However, Zolotukhin *et al.* do not disclose the polynucleotide sequence encoding *R. reniformis* GFP.

Bryan *et al.* teach a nucleic acid molecule encoding a *Renilla* GFP, e.g., *Renilla mulleri* GFP or *Renilla reniformis* GFP (column 57, line 20-column 58, line 17; claims 22-24 of U. S. Patent 6,232,107), and host cells including bacterial, yeast and mammalian host cells, and plasmids for expression of the nucleic acids encoding each luciferase and GFP and combinations of luciferases and GFPs (column 5, lines 30-47; column 9, lines 16-31), where *Renilla* GFP refers to GFPs from the genus *Renilla* and to mutants and variants thereof (column 21, lines 12-14). The reference also teaches a method for

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recombinant production of a Renilla GFP in recombinant cells such as bacterial cells, plant cells and mammalian cells, e.g., human embryonic cells (column 60, line 48-column 61, line 56).

At the time of invention was made, it would have been obvious that one of ordinary skill in the art is motivated to combine the two references to make and use a humanized polynucleotide which encodes Renilla reniformis GFP to produce Renilla reniformis GFP in mammalian cells with high expression as taught by Zolotukhin *et al.* and Bryan *et al.* (claims 1 and 3-5) because the spectrum of Renilla GFP would be preferable to that of Acquorea in many practical applications, since wavelength discrimination between different fluorophores and detection of resonance energy transfer are easier when the component spectra are tall and narrow rather than low and broad (column 16, lines 4-15 of Zolotukhin *et al.*). Thus, the combined references result in the claimed invention and was, as a whole, prima facie obvious at the time the claimed invention was made.

Conclusion

6. No claims are allowed.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached at 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D.
Primary Patent Examiner

 primary **CHIH-MIN KAM
PATENT EXAMINER**

CMK

August 16, 2006